# **Complete Summary**

## **GUIDELINE TITLE**

Screening for type 2 diabetes.

BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2004 Jan; 27(Suppl 1): S11-4. [21 references] PubMed

## **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

## SCOPE

## DISEASE/CONDITION(S)

IDENTIFYING INFORMATION AND AVAILABILITY

Type 2 diabetes mellitus

**GUIDELINE CATEGORY** 

Screening

CLINICAL SPECIALTY

Endocrinology Family Practice Internal Medicine Preventive Medicine

## INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians
Public Health Departments

## GUIDELINE OBJECTIVE(S)

- To review the evidence for and against screening for type 2 diabetes
- To make recommendations regarding screening for type 2 diabetes in asymptomatic adults

## TARGET POPULATION

Asymptomatic adults at risk of developing type 2 diabetes mellitus

These guidelines are <u>not</u> intended for use in the following populations:

- Children
- Adults at risk of developing type 1 diabetes mellitus
- Pregnant women at risk of developing gestational diabetes mellitus

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Assessment of risk factors for diabetes
- 2. Opportunistic screening

Note: Community screening is considered but not recommended.

## Screening Tests

- Plasma glucose (fasting and casual)
- 75-g oral glucose tolerance test

Note: The following tests are considered but not recommended for screening of type 2 diabetes mellitus: glycated hemoglobin (HbA1c), pencil and paper tests such as the American Diabetes Association's risk test, capillary blood glucose testing using a reflectance blood glucose meter.

## MAJOR OUTCOMES CONSIDERED

- Efficacy of screening
- Sensitivity and specificity of screening tests
- Cost effectiveness
- Morbidity and mortality associated with diabetes
- Quality of life

## METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see table below). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

American Diabetes Association's evidence grading system for clinical practice recommendations:

Α

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

\*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

В

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

Ε

Expert consensus or clinical experience

#### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was peer-reviewed, modified, and approved by the Professional Practice Committee and the Executive Committee of the Board of Directors, October 2000.

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The evidence grading system (A through C, E) is defined at the end of the "Major Recommendations" field.

- Evaluation for type 2 diabetes should be performed within the health care setting. Patients, particularly those with a body mass index (BMI) ≥25 kg/m²\*, should be screened at 3-year intervals beginning at age 45; testing should be considered at an earlier age or be carried out more frequently in those who are overweight if additional diabetes risk factors are present (refer to Table 1 in the original guideline document). (E)
- The fasting plasma glucose (FPG) is the recommended screening test. The oral glucose tolerance test may be necessary for the diagnosis of diabetes when the FPG is normal. The FPG is preferred for screenings because it is faster and easier to perform, more convenient, acceptable to patients, and less expensive. (C)
- Diagnostic testing should be performed in any clinical situation in which such testing is warranted; health care providers should not consider whether a person meets screening criteria in such cases. (E)
- Screening outside of health care settings, or community screening, has not been shown to be beneficial and may result in some harm; this type of screening is not recommended. (E)

#### Definitions:

American Diabetes Association's evidence grading system for clinical practice recommendations:

## Α

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

<sup>\*</sup>May not be correct for all ethnic groups.

 Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*

Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

\*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

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- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

Ε

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for the recommendations (see the "Major Recommendations" field).

## POTENTIAL BENEFITS

Decreased morbidity. Early diagnosis after screening may provide an opportunity to prevent morbidity by both improved glycemic management and earlier recognition and treatment of complications.

## POTENTIAL HARMS

Several assumptions about risks may be made.

- False positive screening test. Screening results falsely suggesting disease may expose patients to additional testing, follow-up and treatment that may be inappropriate, bothersome, unpleasant, or hazardous.
- False negative screening test. People with diabetes who have negative screening tests (false negatives) will not receive appropriate diagnostic testing and will be falsely reassured that they are disease-free.
- Physical harm. Exposure to diagnostic tests may result in physical harm (e.g., nausea and vomiting after ingestion of oral glucose load during an oral glucose tolerance test).
- Psychological and social harm. With respect to psychological and social harm, screening may increase worry and reduce health related quality of life.
- Misdiagnosis after screening. Both the sequelae of inappropriate labeling with diabetes and misdiagnosis after screening must be considered. After being diagnosed with diabetes, patients may have difficulty obtaining health insurance or employment.

## QUALIFYING STATEMENTS

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- Evidence is only one component of decision-making. Clinicians care for
  patients, not populations; guidelines must always be interpreted with the
  needs of the individual patient in mind. Individual circumstances such as
  comorbid and coexisting diseases, age, education, disability, and above all,
  patient's values and preferences must also be considered and may lead to
  different treatment targets and strategies. Also, conventional evidence
  hierarchies such as the one adapted by the American Diabetes Association
  may miss some nuances that are important in diabetes care.
- There are no randomized clinical trials documenting the effectiveness of screening programs in decreasing mortality and morbidity from diabetes, and some controversy exists regarding the cost-effectiveness of screening and whether screening as currently carried out is a systematic and ongoing process.
- Based on the lack of data from prospective studies on the benefits of screening and the relatively low cost-effectiveness of screening suggested by existing studies, the decision to test for diabetes should ultimately be based on clinical judgment and patient preference.
- Randomized clinical trials would be the best means to evaluate the benefits and risks of diabetes screening and early treatment. However, rigorous

- studies that apply currently available treatments to a screened group but not to a control group have not been done and are unlikely to be performed soon because of feasibility, ethical concerns, and costs.
- Performance of all screening tests is dependent on the cutoff point selected.
   Unfortunately, there are no well-defined and validated cutoff points to define positive tests.

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Staying Healthy

IOM DOMAIN

**Effectiveness** 

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2004 Jan; 27(Suppl 1): S11-4. [21 references] PubMed

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Oct (republished 2004 Jan)

GUI DELI NE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2004 Diabetes Care Supplement.

## **GUIDELINE COMMITTEE**

Professional Practice Committee

# COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

The guideline was originally approved in October 2000.

American Diabetes Association (ADA) position statements are reissued annually.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>American Diabetes Association (ADA) Website</u>.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Screening for type 2 diabetes (Technical Review). Diabetes Care 2000; 23:1563-80.
- A description of the American Diabetes Association (ADA) clinical practice recommendations and reports and evidence grading system is available in the introduction to the 2002 compilation: Diabetes Care 2002 Jan; 25(Suppl 1):S1-S2.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

#### PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on March 14, 2002, July 29, 2003, and March 23, 2004.

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